Regulations for Implementation of the Drug Administration Law of the People's Republic of China

Decree of the State Council of the People's Republic of China

No. 360

The Regulations for Implementation of the Drug Administration Law of the People's Republic of China are hereby promulgated and shall go into effect as of September 15, 2002.

Premier: Zhu Rongji

August 4, 2002

Regulations for Implementation of the Drug Administration Law of the People's Republic of China

Chapter I
General Provisions

Article 1 The Regulations are formulated in accordance with the Drug Administration Law of the People's Republic of China (hereinafter referred to as the Drug Administration law).

Article 2 The drug regulatory department under the State Council shall establish a national drug testing institute.

The drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government may establish drug testing institutes within its respective administrative area. The plan for the establishment of local drug testing institutes shall be proposed by the drug regulatory department of the people's government of the province, autonomous region and municipality directly under the Central Government and submitted to the people's government of the province, autonomous region and municipality directly under the Central Government for approval.

The drug regulatory department under the State Council and the drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government may, when necessary, designate any testing institute fulfilling the requirements for drug testing to undertake drug testing.

Chapter II
Control over Drug Manufacturers

Article 3 A Drug Manufacturing Certificate shall be acquired for establishment of a drug manufacturer according to the following procedures:

(1) The applicant shall submit an application to the drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government, where the manufacturing site is to be located. The drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government shall, within 30 working days from the date it receives the application, make a review according to the pharmaceutical industry development programs and policies issued by the State and make a decision on approval or disapproval.

(2) After completion of establishment of the planned manufacturer, the applicant shall apply to the original approving department for acceptance inspection. The original approving department shall, within 30 working days from the date it receives the application, arrange an acceptance inspection according to the requirements for the establishment of such manufacturers set forth in Article 8 of the Drug Administration Law; a Drug Manufacturing Certificate shall be issued to the applicant if the inspection is passed. The applicant shall, by holding the Drug Manufacturing Certificate, register with the administrative department for industry and commerce in accordance with law.

Article 4 Any drug manufacturer that intends to alter the approved items in the Drug Manufacturing Certificate shall, 30 days prior to alteration of any approved items, apply to the original certificate-issuing authority for registration of alteration; no approved items may be altered without approval. The original certificate-issuing authority shall make a decision within 15 working days from the date it receives the application. The application shall, by holding the Drug Manufacturing Certificate with altered items, register the alteration with the administrative department for industry and commerce in accordance with law.

Article 5 The drug regulatory department of the people's government at or above the provincial level shall organize inspections of drug manufacturers in accordance with the Good Manufacturing Practice for Pharmaceutical Products (GMP) and the measures and schedule for implementing the GMP formulated by the drug regulatory department under the State Council, and issue a certificate to the manufacturer that complies with the GMP. For the manufacturer producing injections or radioactive pharmaceuticals and for that producing biological products specified by the drug regulatory department under the State Council, the inspection of which shall be conducted by the drug regulatory

department under the State Council. The format of GMP certificate shall be uniformly provided for by the drug regulatory department under the State Council.

Article 6 Any newly-established drug manufacturer or manufacturer with newly –built drug manufacturing workshops or newly-added dosage forms for production shall, within 30 days from the date it obtains the approval documents for manufacturing drug or from the date its formal production is approved, apply to the drug regulatory department for GMP certification as required. The drug regulatory department accepting the application shall, within six months from the date it receives the application, organize inspections as to the compliance with the GMP requirements by the applying manufacturer. A certificate shall be issued to the manufacturer if the inspection is passed.

Article 7 The drug regulatory department under the State Council shall set up a database of GMP inspectors. A GMP inspector shall be qualified as required by the drug regulatory department under the State Council. A GMP inspection shall be conducted by a team of inspectors randomly selected from the database of GMP inspectors according to the provisions of the drug regulatory department under the State Council.

Article 8 The valid term of a Drug Manufacturing Certificate is five years. To continue its drug production, the Certificate holder shall, six months prior to the expiry date of the Certificate, apply for the renewal of the Drug Manufacturing Certificate according to the provisions of the drug regulatory department under the State Council.

Where a drug manufacturer terminates its drug production or is closed down, its Drug Manufacturing Certificate shall be withdrawn by the original certificate-issuing authority.

Article 9 Any drug substance used by a drug manufacturer to produce drug products shall have a drug approval number or an import drug license or a pharmaceutical product license issued by the drug regulatory department under the State Council upon examination, with the exception of Chinese crude drugs and the prepared slices of Chinese crude drugs over which no control by approval number is exercised.

Article 10 In accordance with the provisions in Article 13 of the Drug Administration Law, any drug manufacturer being entrusted with contract production of the drug shall have a GMP certificate corresponding to the contracted drug.

No vaccines, blood products or other drugs specified by the drug regulatory department under the State Council may be contracted for production.

Chapter III

Control over Drug Distributors

Article 11 For establishment of a drug wholesaler, the applicant shall submit an application to the drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government, where the planned drug wholesaler is to be located. The drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government shall, within 30 working days from the date it receives the application, make a decision on approval or disapproval according to the standards for establishment set forth by the drug regulatory department under the State Council. After completion of establishment of the planned wholesaler, the applicant shall apply to the original approving department for acceptance inspection. The original approving department shall, within 30 working days from the date it receives the application, organize an acceptance inspection according to the requirements for establishment of drug distributors set forth in Article 15 or the Drug Administration Law and issue the Drug Supply Certificate to the applicant if the inspection is passed. The applicant shall, with the Certificate, register with the administrative department for industry and commerce in accordance with law.

Article 12 For establishment of a drug retailer, the applicant shall submit an application to the drug regulatory institution of the municipality divided into districts, or to the drug regulatory institution at the county level which is directly set up by the drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government, where the planned retailer is to be located. The drug regulatory institution accepting the application shall, within 30 working days from the date it receives the application, make a decision on approval or disapproval after the review according to the provisions of the drug regulatory department under the State Council, taking into consideration the number of permanent residents, territory, transportation and practical needs in the place. After completion of establishment of the planned retailer, the applicant shall apply to the original approving department for acceptance inspections. The original approving department shall, within 15 working days from the date it receives the application, organize acceptance inspections according to the requirements for establishment of drug distributors set forth in Article 15 of the Drug Administration Law and issue a Drug Supply Certificate if inspections are passed. The applicant shall, with the Certificate, register with the administrative department for industry and commerce in accordance with law.

Article 13 The drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government shall be responsible for the certification of drug distributors. A drug distributor shall, according to the implementing measures and schedule formulated by the drug regulatory department under the State Council, undergo the Good Supply Practice for Pharmaceutical Products (GSP) inspections organized by the local drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government and obtain a GSP certificate. The format of GSP certificate shall be uniformly provided for by the drug regulatory department under the State Council.

Any newly-established drug wholesaler or retailer shall, within 30 days from the date it obtains the Drug Supply Certificate, apply for the GSP certification to the drug regulatory department or institution

which has issued it the Drug Supply Certificate. The drug regulatory institution accepting the drug retailer's application for certification shall, within seven working days from the date it receives the application, transfer the application to the drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government, which is responsible for organizing inspections of drug distributors. The drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central government shall, within three months from the date it receives the application, organize inspections of the drug wholesaler or retailer as to its compliance with the GSP according to the provisions of the drug regulatory department under the State Council and issue a GSP certificate to the drug wholesaler or retailer passing the inspections.

Article 14 A database of GSP inspectors shall be set up by the drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government. A GSP inspector shall be qualified as required by the drug regulatory department under the State Council. A GSP inspection shall be conducted by a team of inspectors randomly selected from the said database according to the provisions of the drug regulatory department under the State Council.

Article 15 The State adopts a classification system for prescription drugs and non-prescription drugs. The State subdivides non-prescription drugs into Class A drugs and Class B drugs according to the level of safety.

Any drug retailer distributing prescription drugs or Class A non-prescription drugs shall have licensed pharmacists or other pharmaceutical technicians whose qualifications are legally recognized. Any retailer distributing Class B non-prescription drugs shall have pharmacy staff members who have passed the examination organized by the local drug regulatory institution of the municipality divided into districts or by the local drug regulatory institution at the county level which is directly set up by the drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government.

Article 16 Any drug distributor that intends to alter the approved items in the Drug Supply Certificate shall, 30 days prior to the alteration of any approved items, apply to the original certificate-issuing authority for registration of alteration; no approved items may be altered without approval. The original certificate-issuing authority shall make a decision within 15 working days from the date it receives the application. The application shall, by holding the Drug Supply Certificate with the altered items, register the alteration with the administrative department for industry and commerce in accordance with law.

Article 17 The valid term of a Drug Supply Certificate is five years. To continue its drug distribution, the Certificate holder shall, six months prior to the expiry date of the Certificate, apply for the renewal of the Drug Supply Certificate according to the provisions of the drug regulatory department under the State Council.

Where a drug distributor terminates its drug distribution or is closed down, its Drug Supply Certificate shall be withdrawn by the original certificate-issuing authority.

Article 18 Where there is no drug retailers at town or country fairs in remote areas with poor communications, the local drug retailers may, after obtaining approval from the local drug regulatory institution of the county (municipality) and being registered with the administrative department for industry and commerce, set up stores at the fairs to sell non-prescription drugs within the approved scope for drug distribution.

Article 19 Drug manufacturers, drug distributors and medical institutions engaged in on-line drug transactions through Internet and the drugs so transacted shall be in conformity with the provisions in the Drug Administration Law and in the Regulations. The measures for administration of on-line drug distribution services shall be formulated by the drug regulatory department under the State Council jointly with the other relevant departments under the State Council.

Chapter IV
Control over Pharmaceuticals in Medical Institutions

Article 20 To establish a pharmaceutical preparation unit in a medical institution, an application shall be submitted to the local health administrative department of the people's government of the province, autonomous region or municipality directly under the Central Government, and, after being consented upon examination, be presented to the drug regulatory department of the people's government at the same level for review and approval. Approval shall be given to the medical institution if it passes the review by the said drug regulatory department and a Pharmaceutical Preparation Certificate for Medical Institution shall be issued to it.

The health administrative department and the drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government shall, within 30 working days from the dates they receive the application respectively, make their own decisions whether or not to consent or approve the application accordingly.

Article 21 Any medical institution that intends to alter the approved items in the Pharmaceutical Preparation Certificate for Medical Institution shall, 30 days prior to the alteration of any approved items, apply to the original examining and approving departments for registration of alteration according to the provisions in Article 20 of the Regulations; no approved items may be altered without approval. The original examining and approving departments shall make their own decisions within 15 working days from the dates they receive the application respectively.

Any medical institution which intends to add new dosage forms or change dispensing sites shall, after passing the acceptance inspection by the local drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government, go through

the registration of alteration of the Pharmaceutical Preparation Certificate for Medical Institution according to the provisions in the preceding paragraph.

Article 22 The valid term of a Pharmaceutical Preparation Certificate for Medical institution is five years. To continue dispensing a pharmaceutical preparation, the medical institution shall, six month prior to the expiry date of the Certificate, apply for the renewal of the Pharmaceutical Preparation Certificate for Medical Institution according to the provisions of the drug regulatory department under the State Council.

Where a medical institution terminates dispensing Pharmaceutical Preparations or is closed down, its Pharmaceutical Preparation Certificate for Medical Institution shall be withdrawn by the original certificate-issuing authority.

Article 23 To dispense a pharmaceutical preparation, the medical institution shall submit the dossier and samples according to the provisions of the drug regulatory department under the State Council, and the pharmaceutical preparation may only be dispensed after being approved by the local drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government and being issued a pharmaceutical preparation approval number.

Article 24 No pharmaceutical preparations dispensed by medical institutions may be marketed or marketed in disguised forms, nor may any advertisement of such pharmaceutical preparations be released.

When a major disaster, epidemic situation or any other emergency occurs, or there is an urgent need clinically but no supply of the needed drug in market, the pharmaceutical preparations dispensed by a medical institution may be subject to transfer allocation and use by other designated medical institutions within a specified time limit, upon approval by the drug regulatory department under the State Council or by the drug regulatory department of the people's government of a province, autonomous region or municipality directly under the Central Government.

Transfer allocation and use of special pharmaceutical preparations regulated by the drug regulatory department under the State Council, and the transfer allocation and use of pharmaceutical preparations dispensed by medical institutions among provinces, autonomous regions, or municipalities directly under the Central Government shall be subject to the approval by the drug regulatory department under the State Council.

Article 25 Pharmacy personnel of medical institutions who check and dispense prescriptions shall be the pharmaceutical technicians whose qualifications are legally recognized.

Article 26 When purchasing drugs, medical institutions shall keep the authentic and complete records. In purchase records shall be indicted the adopted name of the drug in China, dosage form, strength, batch number, date of expiry, manufacturer, supplier, purchase volume, purchase price,

date of purchase and other items specified by the drug regulatory department under the State Council.

Article 27 Drugs provided to patients by medical institutions shall be within the scope of diagnoses and treatments and dispensed according to the prescriptions of licensed doctors or licensed assistant doctors.

The scope of drugs purchased and provided to patients by family planning technical service institutions shall be in conformity with the scope of services approved and the drugs shall be dispensed according to the prescriptions of licensed doctors or licensed assistant doctors.

Out-patient departments, clinics and any other medical institutions, which are set up by individuals, may not purchase or provide drugs other than those commonly used and those for emergency treatment. The range and category of the drugs commonly used and those for emergency treatment shall be determined by the local health administrative department of the people's government of the province, autonomous region, or municipality directly under the Central Government jointly with the drug regulatory department at the same level.

Chapter V
Control over Drugs

Article 28 Institutions for non-clinical safety evaluation and study of drugs shall implement the Good Laboratory Practice for Non-Clinical Laboratory Studies (GLP) and institutions for drug clinical trial shall implement the Good Clinical Practice (GCP). The GLP and GCP shall be formulated by the drug regulatory department under the State Council through respective consultation with the science and technology administrative department under the State Council and the health administrative department under the State Council.

Article 29 Clinical trials, manufacturing or importation of drugs shall be in conformity with the provisions in the Drug Administration Law and in the Regulations, and shall be reviewed and approved by the drug regulatory department under the State Council. The drug regulatory department under the State Council may authorize the drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government to conduct site inspection of research and development conditions of the drugs being applied, to conduct preliminary review of the submitted dossier, and to test the pilot samples. The specific measures therefore shall be formulated by the drug regulatory department under the State Council.

Article 30 Any clinical trial to be conducted for research and development of a new drug shall be subject to the approval by the drug regulatory department under the State Council in accordance with the provisions in Article 29 of the Drug Administration Law.

When an application for conducting clinical trials is approved by the drug regulatory department under the State Council, the applicant shall select institutions for clinical trials from the lawfully certified ones to conduct the trials, and make a report thereof to the drug regulatory department and health administrative department under the State Council for the record.

Prior to the drug clinical trial, the institution for drug clinical trial shall provide the subjects or their guardians with the truthful information on the trial, and obtain a written informed consent

Article 31 For production of a drug admitted by national drug standards, an application shall, in accordance with the provisions of the drug regulatory department under the State Council, be submitted to the drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government or to the drug regulatory department under the State Council, and the relevant technical data and supporting documents shall be provided. The drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government shall, within 30 working days from the date it receives the application, review and make comments, and report the matter to the drug regulatory department under the State Council for review while notifying the applicant of its comments. If all the requirements are fulfilled upon review, a drug approval number shall be issued by the drug regulatory department under the State Council.

Article 32 Where a drug is produced according to an interim standard, an application shall be submitted for formalization of the standard three months prior to the expiry date of the interim standard according to the provisions of the drug regulatory department under the State Council; the drug regulatory department under the State Council shall, within 12 months from the expiry date of the interim standard, review and approve the interim standard as formal one if it fulfills the requirements for the formalization set forth by the drug regulatory department under the State Council. Where an applicant does not make such an application or the original interim standard fails to fulfill the requirements for the formalization, the drug regulatory department under the State Council shall withdraw the interim standard and the approval number for drug production issued on the basis of the said interim standard.

Article 33 For alteration of any items indicated in the approval documents and their attachments for new drug research and development, production or importation of a drug, a supplementary application shall be submitted to the drug regulatory department under the State Council; if all the requirements are fulfilled upon review, an approval shall be given by the drug regulatory department under the State Council.

Article 34 The drug regulatory department under the State Council may, based on the needs for protection of public health, set an observation period of not more than five years for a new drug produced by a drug manufacturer; and no approval shall be given to any other manufacturer to produce or import the said drug during the observations period.

Article 35 The State protects undisclosed data of drug study and others which are independently acquired and submitted by drug manufacturers or sellers to obtain production or marketing approval of the drugs in question which contain new chemical entities. No one may make unfair commercial use of the said data.

Within six years from the date a drug manufacturer or seller obtains the approval documents for producing or marketing a drug containing new chemical entities, if any other applicant uses the data mentioned in the preceding paragraph to apply for approval for production or marketing of the drug in question without permission of the original applicant who has obtained the approval, no approval may be given to any other applicant by the drug regulatory department except that the data submitted are acquired independently.

No drug regulatory department may disclose the data set forth in the first paragraph of this Article except

(1) for the need of public interests; or

(2) where steps are taken to ensure that the data are protected against unfair commercial use.

Article 36 Any drug applied to be imported shall be the one obtained marketing authorization in the country or region of manufacturing. A drug without such an authorization may be approved of its importation in accordance with the provisions in the Drug Administration Law and in the Regulations, provided that its safety, efficacy and clinical needs have been confirmed by the drug regulatory department under the State Council.

For importation of a drug, an application for registration shall be made according to provisions of the drug regulatory department under the State Council. A drug may only be imported after an Import Drug License is given if it is produced by a foreign manufacturer, or a Pharmaceutical Product License is given if it is produced by a manufacturer in Hong Kong, Macao or Taiwan of China.

Article 37 Any medical institution that urgently needs to import a small amount of drugs shall, with a Practicing License of Medical Institution, submit an application to the drug regulatory department under the State Council, and the drugs in question may only be imported upon approval. Such import drugs shall only be used in the designated medical institution for specified purpose.

Article 38 After import drugs arrive at the port, the drug importer shall file a record with the local drug regulatory department in the place where the port is located with the Import Drug License or Pharmaceutical Product License, the original copy of the certificate or origin, duplicate copy of the purchase contract, packing list, bill of freight, shipping invoice, certificate of analysis for the release of drugs by the manufacturer, inset sheet and other documents. The said drug regulatory department shall review the documents submitted and issued a Drug Import Note if they comply with the requirements. The drug importer shall, with the Drug Import Note, complete the formalities for customs declaration and clearance with the Customs.

The drug regulatory department in the place where the port is located shall notify the drug testing institution to conduct sampling and testing of the import drugs on each batch basis with the exception of the circumstances set forth in Article 41 of the Drug Administration Law.

Article 39 Vaccines, blood products, diagnostic reagents in vitro for blood donor screening and other biological products regulated by the drug regulatory department under the State Council shall be subject to testing or review for approval according to the provisions of the drug regulatory department under the State Council before being marketed or imported; any product that fails in testing or has not been approved shall not be marketed or imported.

Article 40 The State encourages cultivation of Chinese crude drugs. Control through approval number shall be exercised over the Chinese crude drugs that can be cultivated or raised on a large scale and in an intensified way and whose quality can be controlled and fulfills the requirements laid down by the drug regulatory department under the State Council.

Article 41 The drug regulatory department under the State Council shall re-evaluate the drugs approved for production and marketing and, on the basis of the re-evaluation results, may take measures to order the revision of insert sheet or suspension of production, marketing or use of a drug, or withdraw the approval documents of drugs with serious adverse reaction or harmful to human health due to other reasons.

Article 42 The valid term of a drug approval number, Import Drug License and Pharmaceutical Product License issued by the drug regulatory department under the State Council is five years. To continue its drug production or importation, the applicant shall submit a re-registration application six months prior to the expiry date. When making re-registration of a drug, the applicant shall submit the relevant data according to the provisions of the drug regulatory department under the State Council. If no application for the re-registration of a drug is made upon expiration of the valid term, or the application fails to comply with the provisions on re-registration of the drug regulatory department under the State Council upon review, the drug approval number, Import Drug License or Pharmaceutical Product License shall be withdrawn.

Article 43 No contents involving prevention, treatment or diagnosis of human diseases shall be included in the package, label or insert sheet and the related promotional materials for promoting a non-drug product, except as otherwise provided by laws or administrative regulations.

Chapter VI
Control over Drug Packaging

Article 44 Immediate packaging materials and containers used by drug manufacturers shall fulfill the requirements for medicinal use and the standards for ensuring human health and safety, and be subject to registration upon approval by the drug regulatory department under the State Council.

The drug regulatory department under the State Council shall be responsible for working out and issuing the measures for control over immediate packaging materials and containers, the product directories and the requirements and standards for medicinal use.

Article 45 Packaging materials and containers selected for production of prepared slices of a Chinese crude drug shall accommodate to drug properties. No prepared slices of a Chinese crude drug may be marketed whose package fails to conform to regulations. A label shall be printed on or attached to the package of prepared slices of a Chinese crude drug.

On the label of prepared slices of a Chinese crude drug shall be indicated the name of the drug, specifications, origin or production, manufacturer, product batch number and production date; if the said drug is controlled by approval number, the drug approval number shall also be indicated.

Article 46 The package, label and insert sheet of a drug shall be printed in accordance with the provisions in Article 54 of the Drug Administration Law and those formulated by the drug regulatory department under the State Council.

The trade name of a drug shall conform to the provisions of the drug regulatory department under the State Council.

Article 47 The immediate packaging materials and containers, used by medical institutions for dispensing pharmaceutical preparations, as well as the labels and insert sheets thereof, shall conform to the provisions in Chapter VI of the Drug Administration Law and the relevant provisions in the Regulations, and be subject to approval by the drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government.

Chapter VII
Control over Drug Pricing and Advertising

Article 48 For drug pricing, the State exercises a system under which the prices are fixed or guided by the government or regulated by the market.

For drugs listed in the directory of drugs for national basic medical insurance and drugs not listed in the directory but monopolistically manufactured and distributed, their prices shall be fixed or guided by the government; the prices of other drugs shall be regulated by the market.

Article 49 For a drug whose price is fixed or guided by the government according to law, the competent pricing department of the government shall fix and adjust its sale prices in accordance with the principle set forth in Article 55 of the Drug Administration Law; and, in fixing and adjusting its sale price, control over the average social rate of drug sales cost, drug sales profit margin, and the differential rate in drug circulation shall be manifested. The specific pricing measures shall be

formulated by the competent pricing department under the State Council in accordance with the relevant provisions in the Pricing Law of the People's Republic of China (hereinafter referred to as the Pricing Law).

Article 50 For a drug whose price shall be fixed or guided by the government and is so established, the competent pricing department shall publish the said price and specify the date for going into effect in designated publications in accordance with the provisions in article 24 of the Pricing Law.

Article 51 For a drug whose price is fixed or guided by the government, the competent pricing department shall, in fixing or adjusting the price, organize experts in pharmaceutical, medical, economic and other fields to conduct assessment; and, if necessary, it shall solicit comments from drug manufacturers, drug distributors, medical institutions, citizens and other relevant units and persons.

Article 52 The competent pricing department of the government may, in practicing drug price monitoring according to the provisions in Article 28 of the Pricing Law, appoint certain drug manufactures, drug distributors and medical institutions as drug price monitoring units for the purpose of understanding and analyzing the changes and trends of drug prices; the appointed units shall provide cooperation, support and truthful information.

Article 53 For publishing a drug advertisement, the relevant materials shall be submitted to the local drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government where the drug manufacturer is located. The drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government shall, within ten working days after it receives the relevant materials, make a decision upon review on whether to issue the approval number for drug advertisement. Where the approval number for drug advertisement is issued upon review, a record shall be filed with the drug regulatory department under the State Council concurrently. The specific measures for drug advertisement shall be formulated by the drug regulatory department under the State Council.

For publishing an advertisement for an import drug, an application for approval number for drug advertisement shall be submitted to the local drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government where the drug import agency is located, in accordance with the provisions in the preceding paragraph of this Article.

For publishing an advertisement in a province, autonomous region or municipality directly under the Central Government other than the place where the drug manufacturer or drug import agency is located, any enterprise publishing advertisement shall file a record in advance with the drug regulatory department of the province, autonomous region or municipality directly under the Central Government where the advertisement is to be published. If the drug regulatory department of the province, autonomous region or municipality directly under the Central Government accepting the

record finds that the approved contents of the drug advertisement does not conform to the provisions on the control of drug advertisement, it shall turn over the matter to the original verifying and issuing department for handling.

Article 54 For a drug whose production, marketing or use is ordered to be suspended upon decision of the drug regulatory department under the State Council or of the drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government, no advertisement for the drug may be published during the period of suspension; where such an advertisement is already published, the publication shall be discontinued immediately.

Article 55 Any enterprise publishing advertisement, advertising agent or advertisement publisher shall immediately discontinue the publication of any drug advertisement without approval by the drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government, or whose approval number for drug advertisement is forged, or belongs to others, or is expired, or, whose approval number for drug advertisement is canceled because of other illegal advertising activities.

Where a drug advertisement is published in violation of law and the circumstances are serious, the drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government may announce the matter to the public.

Chapter VIII
Inspection of Drugs

Article 56 The Drug regulatory department (including the drug regulatory institution legally established by the drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government, the same below) shall supervise and inspect the research and development, production, distribution and use of drugs in accordance with law.

Article 57 Sampling of a drug shall be conducted by two or more persons who are responsible for drug supervision and inspection in accordance with the provisions of the drug regulatory department under the State Council.

The party whose drug is to be sampled shall provide samples of the drug for testing and may not refuse. Where the party whose drug is to be sampled refuses the sampling and testing of the drug without justifiable reasons, the drug regulatory department under the State Council and the drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government where it is located may announce a stop to marketing and use of the drug, of which the sampling and testing are refused.

Article 58 Where a drug is suspected of being impure or adulterated but unable to be tested by testing method and through the testing items prescribed in the national drug standards, the drug testing institution may conduct tests by adding testing methods and items upon approval by the drug regulatory department under the State Council, the testing results obtained by using the additional testing methods and items may be taken as the basis for certifying the quality of the drugs.

Article 59 The drug regulatory department under the State Council and the drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government shall regularly make announcements on drug quality according to the results of sampling and testing. In a drug quality announcement shall be included the names of sampled drugs, sources of the samples, their manufacturers, batch numbers, drug strength, testing institutions, drug specifications, results of testing, and items failing to pass the test, etc. If a drug quality announcement is improperly made, the department making the announcement shall, within five days from the date of recognition of the improper announcement, make a correction within the scope in which the original one is made.

Where the party has any objection to the results of testing conducted by the drug testing institution and applies for re-testing, it shall submit a written application and the original testing report to the drug testing institution responsible for re-testing. The sample for re-testing shall be taken form the retaining sample kept by the original testing institution.

Article 60 Where the drug regulatory department takes administrative enforcement measures to seal or seize drugs that have been proved potentially harmful to human health and the related evidentiary materials, it shall, within seven days from the date it takes such measures, make a decision on whether or not to file a case; where it is necessary to test such drugs, it shall, within 15 days from the date the testing report is issued, make a decision whether or not to file a case; where the conditions for filing a case are not met, the administrative enforcement measures shall be withdrawn; where the marketing and use of such drugs need to be suspended, a decision shall be made by the drug regulatory department under the State Council or the drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government.

Article 61 No fees may be charged for selective drug sampling and testing.

Where the party has any objection to the results of testing conducted by the drug testing institution and applies for re-testing, it shall pay in advance the fees for drug testing to the drug testing institution responsible for the re-testing according to the provisions of the drug regulatory department under the State Council or of the drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government. If the results of re-testing are inconsistent with the original testing results, the fees for the re-testing shall be paid by the original testing institution.

Article 62 Fees may be collected for certificate issuance, drug registration, drug certification, drug testing for approval and mandatory drug testing according to the provisions in the Drug Administration Law and in the Regulations. The specific standards for collecting fees shall be formulated by the finance department under the State Council and the competent pricing department under the State Council.

Chapter IV
Legal Liabilities

Article 63 A drug manufacturer or distributor shall be punished by the drug regulatory department according to the provisions in Article 79 of the Drug Administration Law under any of the following circumstances:

(1) where any newly-established drug manufacturer or any manufacturer with a newly-built workshop or with newly-added dosage forms fails in the GMP certification within the time limit prescribed by the drug regulatory department under the State Council but is still engaged in drug production.
(2) where any newly-established drug distributor fails in GSP certification within the time limit prescribed by the drug regulatory department under the State Council but is still engaged in drug distribution.

Article 64 Any contract giver or acceptor, in violation of the provisions in Article 13 of the Drug Administration Law, giving or accepting the contract for drug production without authorization shall be punished in accordance with the provisions in Article 74 of the Drug Administration Law.

Article 65 Where, without approval, anyone who sets up a store to sell drugs at the town or country fairs, or sells drugs in a store at the fairs beyond the approved scope of drug distribution, shall be punished according to the provisions in Article 73 of the Drug Administration Law.

Article 66 Any medical institution that uses pharmaceutical preparations dispensed by other medical institutions without approval shall be punished according to the provisions in Article 80 of the Drug Administration Law.

Article 67 Any out-patient department, clinic or any other medical institution, which is set up by individuals, if providing patients with drugs beyond the defined scope or kinds of drugs, shall be punished according to the provisions in Article 73 of the Drug Administration Law.

Article 68 Any medical institution that uses counterfeit and substandard drugs shall be punished according to the provisions in Article 74 and 75 of the Drug Administration Law.

Article 69 Any institution, in violation of the provisions in Article 29 of the Drug Administration Law, conducting a drug clinical trial without approval shall be punished according to the provisions in Article 79 of the Drug Administration Law.

Article 70 Where an applicant, in applying for conducting a drug clinical trail, submits false data on drug production procedures, quality specifications, or results of pharmacological and toxicological studies, etc., or submits fraud samples, the drug regulatory department under the State Council shall disapprove the application and give a warning to the applicant; where the circumstances are serious, no application for clinical trial of the said drug submitted by the said applicant may be accepted within three years.

Article 71 Where anyone producing prepared slices of Chinese crude drugs without the national drug standard fails to comply with the processing procedures formulated by the drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government, or any medical institution dispensing pharmaceutical preparations fails to comply with the standards approved by the drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government, punishment shall be imposed thereupon according to the provisions in Article 75 of the Drug Administration Law.

Article 72 Where the drug regulatory department and its staff members, in violation of regulations, release undisclosed experimental data or other materials submitted by a manufacturer or seller for obtaining approval of production or marketing of a drug containing new chemical entities, thus resulting in losses to the applicant, the drug regulatory department shall be liable for compensation in accordance with law. After compensating the losses, the drug regulatory department shall order the staff members who disclose the said data in purpose or have serious negligence to partially or fully bear the compensation and shall also impose administrative sanctions on those who are directly liable therefor.

Article 73 Any drug manufacturer or distributor producing or distributing drugs or any medical institution dispensing pharmaceutical preparations, whose package, labels or inset sheets are in violation of the provisions in the Drug Administration Law and in the Regulations, shall be punished according to the provisions in Article 86 of the Drug Administration Law.

Article 74 Any drug manufacturer, distributor or medical institution altering any items licensed for manufacturing, distributing, or dispensing drugs without completing the formalities for registration of alteration as required shall be given a warning by the original certificate-issuing department and be ordered to complete the said formalities within a time limit. Its Drug Manufacturing Certificate, Drug Distribution Certificate or Pharmaceutical Preparation Certificate for Medical Institution shall be announced as nullified if it fails to do so within the time limit, and punishment shall be given according to the provisions in Article 73 of the Drug Administration Law if it continues its production and distribution activities.

Article 75 Anyone violating the provisions in Article 48, 49, 50, 51 or 52 of the Regulations concerning the control over drug pricing shall be punished according to the relevant provisions in the Pricing Law.

Article 76 Where the approved content of a drug advertisement is altered without authorization, the advertiser shall be ordered by the drug regulatory department to discontinue publishing the said advertisement without delay, and punishment shall be given by the original approving drug regulatory department according to the provisions in Article 92 of the Drug Administration Law.

After the drug regulatory department withdraws the drug advertisement approval number, it shall notify the organ in charge of advertising supervision and control of the matter within five working days from the date the administrative decision is made. The organ in charge of advertising supervision and control shall, within 15 working days from the date it receives the notification from the drug regulatory department, make an administrative decision for handling the matting according to the relevant provisions in the Advertisement Law of the People's Republic of China.

Article 77 Where any enterprise published a drug advertisement outside the province, autonomous region or municipality directly under the Central Government where the drug manufacturer or drug import agency is located without filing a record with the drug regulatory department of the province, autonomous region or municipality directly under the Central Government where the drug advertisement is published, the drug regulatory department of the province, autonomous region or municipality directly under the Central Government shall order the enterprise to make a rectification within the time limit. If the enterprise fails to make any rectification within the time limit, advertising activities carried out in the place for the said drug shall be discontinued.

Article 78 Where the drug regulatory department finds that a drug advertisement is published without approval by the drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government, the drug regulatory department shall notify the organ in charge of advertising supervision and control to investigate and handle the matter in accordance with law.

Article 79 Where anyone that, in violation of the provisions in the Drug Administration Law and in the Regulations, commits any of the following acts shall be given heavier punishment by the drug regulatory department based on the extent of punishment in the Drug Administration Law and in the Regulations:

(1) passing narcotics, psychotropic substances, medicinal toxic drugs and radioactive pharmaceuticals off as other drugs or vice versa;
(2) producing or selling counterfeit or substandard drugs of which the main users are pregnant and parturient women, infants and children;
(3) producing or selling biological and blood products which are defined as counterfeit or substandard drugs;
(4) producing, selling or using counterfeit or substandard drugs, thus inducing harmful results to people;
(5) producing, selling or using counterfeit or substandard drugs again after being punished; or
(6) refusing or evading supervision and inspection, or forging, destroying or concealing relevant evidentiary materials, or using sealed and seized articles without authorization.

Article 80 Branches of drug regulatory departments shall have the authority to, according to the provisions in the Drug Administration Law and in the Regulations, give administrative punishments such as warning, fine and confiscation of drugs illegally produced or marketed and illegal gains therefrom.

Article 81 Where a drug distributor or medical institution dose not violate the relevant provisions in the Drug Administration Law and in the Regulations and has sufficient evidence to prove its unawareness that the drugs being sold or used are counterfeit or substandard drugs, the said drugs and illegal gains therefrom shall be confiscated; however, it may be exempted from other administrative punishments.

Article 82 Articles confiscated according to the provisions in the Drug Administration Law and in the Regulations shall be dealt with under supervision by drug regulatory departments in accordance with provisions.

Chapter X
Supplementary Provisions

Article 83 The terms used in the Regulations are defined as follows:

Drug quality attachment and other marks refer to approval documents for drug production, drug testing reports, drug packages, labels and insert sheets.

New drugs refer to the drugs which have not been marketed within the territory of the People's Republic of China.

Prescription drugs refer to the drugs that may only be purchased, dispensed or used with prescriptions by licensed doctors or licensed assistant doctors.

Non-prescription drugs refer to the drugs announced by the drug regulatory department under the State Council which can be purchased or used by consumers upon their own judgment without prescriptions by licensed doctors or licensed assistance doctors.

Pharmaceutical preparations in medical institutions refer to pharmaceutical preparations based on fixed prescriptions which have been dispensed upon approval by medical institutions according to their own clinical needs for their own use.

Drug certification refers to the process through which the drug regulatory department inspects and evaluates the units engaging in research and development, production, distribution or use of drugs as to their compliance with corresponding requirements, and decides on whether to issue the corresponding certificates.

Drug distribution refers to drug wholesale and/or retail.

Scope for drug distribution refers to the category of drugs reviewed and approved for distribution by the drug regulatory department.

Drug wholesalers refer to the drug distributors who sell the purchased drugs to drug manufacturers, drug distributors or medical institutions.

Drug retailers refer to the drug distributors who sell the purchased drugs to consumers directly.

Article 84 The term “drugs to be marketed in China for the first time” used in Article 41 of the Drug Administration Law refers to the drugs that are marketed for the firs time in China by domestic or foreign drug manufacturers, including the same product manufactured by different drug manufacturers.

Article 85 In the second paragraph of Article 59 of the Drug Administration Law, “drug manufacturers, drug distributors or their agents are prohibited from offering, under any pretence, money or things of value or other benefits to leading members, drug purchasers, physicians, or other related persons of the medical institutions where their drugs are used”, the term “money or things of value or other benefits” refer to the illegitimate benefits provided by drug manufacturers, drug distributors or their agents to leading members, drug purchasers , physicians, or other related persons of the medical institutions for the purpose of influencing their acts in purchasing or prescribing drugs.

Article 86 The Regulations shall go into effect as of September 15, 2002.